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09/586,704

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Ralph M. Steinman

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LAHIVE & COCKFIELD, LLP  
FLOOR 30, SUITE 3000  
ONE POST OFFICE SQUARE  
BOSTON, MA 02109

EXAMINER

SCHWADRON, RONALD B

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/586,704	<b>Applicant(s)</b> STEINMAN ET AL.	
	<b>Examiner</b> Ron Schwadron, Ph.D.	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22,23,26-30 and 35-45 is/are pending in the application.
- 4a) Of the above claim(s) 22,23,29 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-28,35-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/30/08 and 2/23/09 and 8/31/09 and 10/13/09</u> . | 6) <input type="checkbox"/> Other: ____.  |

1. Claims 26-28,35-45 are under consideration.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 26-28,35-45 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been considered and deemed not persuasive.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . . claimed subject matter", *Vas-Cath, Inc. V. Mahurkar*, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the conjugate recited in the claimed composition.

The instant claims recite use of an antiDEC antibody which binds human DEC-205. The term human DEC-205 would appear to encompass full length human DEC-205 as well as mutants and variants or alleles of said human protein (for example see specification, page 28). However, only full length murine DEC-205 protein is disclosed in the specification of the parent application. The sequence listing discloses two peptides derived from human DEC 205 of 30 and 25 amino acids respectively. However, human DEC-205 contains approximately 1800 amino acids. There is no disclosure in the specification of the identity of the approximately 1750 other amino acids or purified human DEC-205.

Thus, whilst the specification of discloses murine DEC-205 protein, the term human DEC-205 would appear to encompass full length human DEC-205 and undescribed mutants and variants or alleles of said human protein. Thus, the claims

would encompass use of antibodies which bound full length human DEC-205 as well as undescribed mutants and variants or alleles of human DEC-205. Regarding claim 40, in the absence of human DEC-205, it would not be possible to establish which antibodies reacted with human DEC-205.

In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In *University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, *id.* at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", *Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd.*, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein is stated:

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicants comments and the Nussenzweig declaration, the cloned human DEC-205 sequence referred to is not disclosed in the specification of the instant application. Regarding the amended claims, human DEC-205 is approximately 1800 amino acids in length. The recitation in the claim of a 30 or 25 amino acid sequence derived from said molecule in itself does not provide written description of a molecule that is almost 1800 amino acids in length. The claims encompass use of antibodies which bind any immunogenic epitope on the approximately 1775 undisclosed amino acids of DEC 205 and the specification does not disclose the identity of said amino acids or disclose purified human DEC-205 protein. Regarding Figure 6 in parent application 09/586704 (and the reference to said Figure in pages 10 and 56 of the specification), said Figure refers to experiments performed in mice, not humans. Regarding claims 40-45, said claims still require use of human DEC-205 to determine if the antibodies cross react with human DEC-205.

Regarding applicants comments about isolating human DEC-205 (wherein isolated human DEC-205 is not disclosed in the specification), attention is directed to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein is stated:

The description requirement of the patent statute requires a description of an invention, **not an indication of a result that one might achieve if one made that invention.** See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Regarding applicants comments about *Capon v. Eshhar* (CAFC August, 2005), the invention under consideration in said case was a conjugate that used two known components. The invention was the conjugate, not the components. The components of the conjugate (scFv and transmembrane/cytoplasmic domain of a portion that triggers cell activation) were well known in the art. Thus, their invention was a conjugate using components well known in the art. Thus, said decision is not relevant to the claims under consideration wherein Human DEC-205 was not known in the art (it had not been isolated or sequenced).

Regarding applicants comments about claims 35-39, said claims recite use of an antihuman DEC 205 antibody which binds an amino acid sequence "as set forth" in SEQ. ID. No. 1 and wherein said language is interpreted as equivalent in scope to comprising. Therefore said claim could be interpreted as encompassing antibodies which bound the sequence comprising said amino acid sequence. Regarding claim 40, in the absence of human DEC-205, it would not be possible to establish which antibodies reacted with human DEC-205.

4. Claims 26-28,35-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been considered and deemed not persuasive.

There is no support in the specification for the recitation of "human DEC-205 protein comprising an amino acid sequence as set forth in SEQ ID 1 in claim 26/35. Whilst the specification discloses SEQ ID NO 7 as a peptide derived from DEC 205, there is no disclosure in the specification as originally filed of a DEC-205 protein comprising said peptide wherein the molecule could have any amino acids in association with the aforementioned sequences recited in the claim. There is no written description in the specification as originally filed for the scope of the claimed invention (e.g. the claimed invention constitutes new matter). Regarding the various cited passages of the specification, none of the passages disclose human DEC-205 protein comprising an amino acid sequence as set forth in SEQ ID 7 in claim 6/13. Whilst the specification discloses SEQ ID NO 7 as a peptide derived from DEC 205, there is no disclosure in the specification as originally filed of a DEC-205 protein comprising said peptide wherein the molecule could have any other amino acids in association with the aforementioned sequences recited in the claim.

There is no written description of the scope of the claimed invention in the specification as originally filed (aka the claimed inventions constitute new matter).

Regarding applicants comments, there is no support in the specification as originally filed for the recitation of "human DEC-205 protein comprising an amino acid

sequence as set forth in SEQ ID 1 in claim 26/35. Whilst the specification discloses SEQ ID NO 7 as a peptide derived from DEC 205, there is no disclosure in the specification as originally filed of a DEC-205 protein comprising said peptide wherein the molecule could have any amino acids in association with the aforementioned sequences recited in the claim. There is no written description in the specification as originally filed for the scope of the claimed invention (e.g. the claimed invention constitutes new matter). Regarding the various cited passages of the specification, none of the passages disclose human DEC-205 protein comprising an amino acid sequence as set forth in SEQ ID 7 in claim 6/13. Whilst the specification discloses SEQ ID NO 7 as a peptide derived from DEC 205, there is no disclosure in the specification as originally filed of a DEC-205 protein comprising said peptide wherein the molecule could have any other amino acids in association with the aforementioned sequences recited in the claim.

Regarding applicants comments, as per the previous Office Action, section 5, "There is no written description of the scope of the claimed invention in the specification as originally filed (aka the claimed inventions *constitute new matter*).".

5. Claims 26,27,35,36,39,40,43-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the claimed composition that lacks an immune stimulator. The specification and original claims disclose a composition with the conjugate recited in the claims and an immune stimulator, but do not disclose a vaccine without an immune stimulator.

There is no written description of the scope of the claimed invention in the specification as originally filed (aka the claimed inventions constitute new matter).

6. Claims 26-28,35-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. Applicants arguments have been considered and deemed not persuasive.

The specification is not enabling for the claimed vaccine. The specification does not disclose how to use the instant invention for the in vivo treatment or prevention of disease in humans. Applicant has not enabled the breadth of the claimed invention in view of the teachings of the specification because the use for the instant invention disclosed in the specification is the in vivo treatment/prevention of disease in humans. The state of the art is such that is unpredictable in the absence of appropriate evidence as to how the instant invention could be used for the in vivo treatment/prevention of disease in humans.

Judge Lourie stated in Enzo Biochem Inc. v. Calgene Inc. CAFC 52 USPQ2d 1129 that:

*The statutory basis for the enablement requirement is found in Section 112, Para. 1, which provides in relevant part that:*

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . . 35 U.S.C. Section 112, Para. 1 (1994). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" Genentech, Inc. v. Novo Nordisk, A/S , 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see Hybritech, Inc. v. Monoclonal Antibodies, Inc. , 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), which in this case is October 20, 1983 for both the '931 and '149 patents.*

*We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., Wands , 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the*

*necessity for some experimentation . . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not*



*'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In re Wands , we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows:*

*(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.*

*Id. at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See Amgen, Inc. v. Chugai Pharm. Co., Ltd. , 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").*

Regarding Wands factors 4,5,7,8, the instant invention deals with a vaccine for use in humans. Schjetne et al. disclose that DEC205 antigen conjugates administered in vivo require CD40 ligation in vivo in order to induce an immune response (see page 4169, second column, first paragraph). Thus, the claimed invention would not be expected to induce an immune response because it lacks an agent that causes CD40 ligation. Thus, said invention could not be used to treat disease in human because it does not induce an immune response. Regarding the use of the instant invention as a tumor vaccine, Schjetne et al. discloses that even in the presence of CD40 ligation, that tumor vaccines would be unsuitable for treating tumor bearing animals (see page 4175, first page, last paragraph). The claims encompass a vaccine for treating tumor bearing animals/humans. Furthermore, there is currently no known tumor vaccine that can be used to treat cancer in humans wherein the vaccine utilizes tumor antigens.

As per Wands factor (8), the claims encompass the treatment of disease in humans.

Regarding Wands factors 1-3, there is no disclosure in the specification of any in vivo evidence in any model wherein the claimed invention is used as a vaccine or tumor vaccine. Regarding Wands factor 6, the relative skill of those in the art is high (eg. Ph.D. or M.D.).

It appears that undue experimentation would be required of one skilled in the art

to practice the instant invention using the teaching of the specification. See *In re Wands* 8 USPQ2d 1400(CAFC 1988).

Regarding applicants comments, the MPEP section 2164.01(c) states:

*When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (claiming a chimeric gene capable of being expressed in any cyanobacterium and thus defining the claimed gene by its use).*

The claims under consideration are all vaccines wherein vaccines are used for the treatment/prevention of human disease.

Regarding applicants comments, the quoted passage of Schjetne et al. refers to *physical linkage of antiCD40 antibody and antigen*. It does not disclose that antiCD40 ligation is not required for antigen activation (aka it discloses that in certain circumstances the ligating antibody whilst required need not be attached to the antigen). Schjetne et al. disclose that DEC205 antigen conjugates administered in vivo require CD40 ligation in vivo in order to induce an immune response (see page 4169, second column, first paragraph). Thus, the claimed invention would not be expected to induce an immune response because it lacks an agent that causes CD40 ligation. Thus, said invention could not be used to treat disease in human because it does not induce an immune response. Regarding the use of the instant invention as a tumor vaccine, Schjetne et al. discloses that even in the presence of CD40 ligation, that tumor vaccines would be unsuitable for treating tumor bearing animals (see page 4175, first page, last paragraph). The claims encompass a vaccine for treating tumor bearing animals/humans. Furthermore, there is currently no known tumor vaccine that can be used to treat cancer in humans wherein the vaccine utilizes tumor antigens.

Regarding applicants reference to various publications not related to use of the claimed invention, said references do not address the issues raised by Schjetne et al. Applicants reference to publications that are not of record and of which copies have not been submitted are not addressed. Regarding applicants comments about 09/925284, Schjetne et al. disclose that DEC205 antigen conjugates administered in vivo require CD40 ligation in vivo in order to induce an immune response (see page 4169, second column, first paragraph). The data referred to in 09/925284 is disclosed in the Steinman publications referred to in Schjetne et al. page 4169, second column, first paragraph

(aka 4.9,10). Thus, the claimed invention would not be expected to induce an immune response because it lacks an agent that causes CD40 ligation. Thus, said invention could not be used to treat disease in human because it does not induce an immune response. Regarding the use of the instant invention as a tumor vaccine, Schjetne et al. discloses that even in the presence of CD40 ligation, that tumor vaccines would be unsuitable for treating tumor bearing animals (see page 4175, first page, last paragraph). The claims encompass a vaccine for treating tumor bearing animals/humans. Furthermore, there is currently no known tumor vaccine that can be used to treat cancer in humans wherein the vaccine utilizes tumor antigens.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. The rejection of claim 28 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is (571)272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/  
Ron Schwadron, Ph.D.  
Primary Examiner  
Art Unit 1644